IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA	*	
	*	
v.	*	**CRIMINAL NO. 10-cr-694-RWT**
	*	
LAUREN STEVENS,	*	
	*	
Defendant	*	
	*	
	*	

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THE UNITED STATES' COMMENTS ON THE COURT'S PROPOSED JURY INSTRUCTIONS

Although the United States intends to raise additional comments during the upcoming charging conference, it submits these written comments in order to expedite the conference.

I. Requested additional instructions

The United States intends to respectfully request that the following instructions be added to those proposed by the Court.

1. Element One of Count Two

The Court's instructions do not define the first element of Count Two for the jury. The government requests that the Court add Joint Instruction 33 after page 74 of the Court's Instructions. Joint Instruction 33 reads:

JOINT PROPOSED JURY INSTRUCTION No. 33

(Count Two: Falsification/Concealment of Documents: First Element – Falsification or Concealment of Evidence)

To satisfy its burden of proof as to Count Two, the first element that the government must prove beyond a reasonable doubt is that the defendant altered, falsified, concealed or

covered up a document, record or tangible object. To "falsify" means to make an untrue statement which is untrue at the time made and is known to be untrue at the time made. To "conceal" means to withhold from another. It requires some act to prevent detection of some fact the defendant was required to reveal. To "cover up" means to hide from another.

Sand 36-4 (modified)

2. Venue

The Court's instructions do not include a venue instruction. Once requested by the defendant – as has occurred here – omission of a venue instruction constitutes reversible error. Therefore, the government requests that the Court insert a venue instruction. The government respectfully suggests that this instruction may fit well after page 92 of the Court's proposed instructions.

The government proposes the following text, based on Sand Instruction 3-11 and modified to refer to multiple charges and the confines of the District of Maryland:

GOVERNMENT'S PROPOSED JURY INSTRUCTION ON VENUE

In addition to the foregoing elements of each crime charged, you must consider whether any act in furtherance of the crimes charged occurred within the District of Maryland. The District of Maryland encompasses the entire state of Maryland.

In this regard, the government need not prove that the crime itself was committed in this district or that the defendant herself was present here. It is sufficient to satisfy this element if any act in furtherance of the crime occurred within this district. If you find that the government has failed to prove that any act in furtherance of the crime occurred within this district – or if you have a reasonable doubt on this issue – then you must acquit.

3. Ethics Instruction

The Court has previously indicated that it will instruct the jury regarding the relevant rules of professional conduct, which will make clear to the jury that counseling a client to engage in a crime – or committing a crime on behalf of a client – does not constitute bona fide legal representation, and that the defendant was aware that she could not rely on legal advice counseling her to commit a crime. The United States wishes to clarify that committing a crime, as well as counseling or assisting others to commit a crime, is not good faith legal representation. The government submits that at a minimum the following slightly modified version of the Court's proposed instruction should be used, and requests that it be inserted after page 56 of the Court's proposed jury instructions:

GOVERNMENT PROPOSED JURY INSTRUCTION ON PROFESSIONAL CONDUCT

I hereby instruct you that as a part of representing a client, a lawyer may not commit crimes herself or counsel or assist a client in committing a crime. You may consider this requirement in evaluating whether the defendant's conduct was lawful and good faith representation of a client.

4. Aiding and Abetting

The United States has presented evidence that both the defendant and her company violated Counts One through Six of the Indictment. The United States submits that its proposed instructions on aiding and abetting – included at pages 87-92 of the Court's proposed instructions, but crossed out – are appropriate because a reasonable jury could determine that GSK and others at GSK also committed the crimes charged.

If a corporation commits a crime and an employee or agent aids and abets the corporation

in committing the crime, then the employee or agent may be convicted as an aider and abettor. *United States v. Sain*, 141 F.3d 463, 474-75 (3d Cir. 1998); *United States v. Doig*, 950 F.2d 411 (7th Cir. 1991); *Wood v. United States*, 204 F. 55, 58 (4th Cir. 1913).[1] A narrow exception exists where Congress clearly intended the underlying statute to only criminalize the activity of the corporation, and not that of natural persons. *See Doig*, 950 F.2d 411 (holding that employees cannot be held liable for aiding their employers in violating the Occupational Health and Safety Act of 1970, the text of which provides that only employers are subject to criminal sanctions).

A corporation can be held criminally liable for violating any of the underlying crimes at issue in this case. *See Arthur Andersen LLP v. United States*, 544 U.S. 696 (2005) (corporate liability for § 1512 violations); *United States v. Ionia Mgmt. S.A.*, 555 F.3d 303 (2d Cir. 2009) (corporate liability for § 1519 violations); *United States v. Arch Trading Co.*, 987 F.2d 1087, 1095 (4th Cir. 1993) (corporate liability for § 1001 violations). Furthermore, none of these statutes are limited to corporate liability; they all also criminalize the acts of natural persons. *See United States v. Holstein*, 618 F.3d 610 (7th Cir. 2010) (individual liability for § 1519 violations); *United States v. Lanham*, 617 F.3d 873, 886-87 (6th Cir. 2010) (same); *United States v. Tzueton*, 370 F. App'x 415 (4th Cir. 2010) (unpublished) (individual liability for § 1512(c)(2) violations); *United States v. Peed*, 714 F.2d 7 (4th Cir. 1983) (individual liability for § 1001 violations). Therefore, if the United States demonstrates that GSK violated any of these statutes and that the defendant aided and abetted the company in doing so, then the defendant may be

[1] In accordance with a now-defunct practice, the Fourth Circuit granted a writ of error to provide for Supreme Court review of its decision. *Wood v. United States*, 211 F. 1023 (4th Cir. 1913); *see also* Black's Law Dictionary 1749 (9th ed. 2009) (describing the historical practice). The Supreme Court dismissed the writ without substantive comment, re-instating the Fourth Circuit decision. *Wood v. United States*, 232 U.S. 731 (1914).

convicted of aiding and abetting.

5. Conscious Avoidance

In the event the defendant claims that she was unaware that GSK was engaged in a pattern of off-label marketing, including for weight loss, despite having access to that knowledge, the United States requests Sand Instruction 3A-2 on conscious avoidance. For example, if she claims to not have read the employment file of Greg Thorpe – which she had specifically collected and her notes reflect consideration and discussion of, and which includes specific allegations of systematic off-label marketing of Wellbutrin, including for weigh loss – a reasonable jury could conclude that she consciously avoided that information. Likewise, if to the extent the defendant claims not to have determined whether Drs. Hudziak and Pradko used off-label slides repeatedly, including for weight loss, a jury could determine that the defendant consciously avoided learning of wrongdoing by meeting with Dr. Pradko and not confirming the obvious import of the slides he had submitted. Similarly, to the extent the defendant may claim that she was not familiar with the results of the Marlene May interview (despite her specific notes about that interview), notes reflecting a GSK employee's experience observing a pattern of speakers engaging in off-label promotion, that too could be conscious avoidance.

II. Additional Comments on the Court's Proposed Instructions

1. Off-Label Uses of Prescription Drugs (p. 51)

The United States submits that the Court's proposed instruction on off-label uses of prescription drugs misstates the relevant law and will mislead the jury regarding the charges for which the defendant is on trial. To the extent the Court finds it appropriate to include an instruction on this issue, the government respectfully proposes the following instruction:

GOVERNMENT'S PROPOSED INSTRUCTION ON OFF-LABEL USE

Before addressing the charges against the defendant, I would like to discuss off-label uses of prescription drugs. You have heard evidence about the medical practice of prescribing legally approved prescription drugs for uses not approved by the FDA, or "off-label uses." A licensed practitioner, in the exercise of his or her medical judgment, is permitted to prescribe a drug to a patient for an off-label use. This practice is both legal and medically accepted. In addition, federal law and FDA policy recognize certain limited situations in which a manufacturer is allowed to disseminate scientific information about off-label uses of its products. It is unlawful, however, for a drug manufacturer to promote its drugs for off-label uses or in a manner inconsistent with the drug's approved product labeling.

The defendant in this case is not charged with off-label promotion of prescription drugs.

The defendant's proposed instruction, which the court proposes to adopt, misstates the relevant law. This instruction states that "the FDA recognizes four permissible ways for manufacturers to disseminate off-label information about their drug products." The first enumerated way reads: "First, FDA regulations permit a manufacturer to discuss scientific information about its products, including off-label uses, provided that the manufacturer does not represent in a promotional context that the product is approved for an off-label use." This portion of the instruction relies on a facially incorrect reading of the cited regulation and should be deleted.

The only regulation cited in support of the instruction, 21 C.F.R. § 312.7, does not support such a broad statement and does not apply to the facts of this case. That regulation

reads, in relevant part, as follows:

> A sponsor or investigator, or any person acting on behalf of a sponsor or investigator, shall not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug. This provision is not intended to restrict the full exchange of scientific information concerning the drug, including dissemination of scientific findings in scientific or lay media. *Rather, its intent is to restrict promotional claims of safety or effectiveness of the drug for a use for which it is under investigation and to preclude commercialization of the drug before it is approved for commercial distribution.*

21 C.F.R. § 312.7(a) (2002 edition) (emphasis added). The 2001 edition is identical.

This provision appears in Part 312 of Title 21, "Investigational New Drug Application," and the regulation itself is titled "Promotion and charging for investigational drugs." On its face, this provision applies only to investigational new drugs. The terms "investigational new drug" and "investigational drug," as used in the regulation, refer to "a new drug or biological drug that is used in a clinical investigation." 21 C.F.R. § 312.3(b). (These clinical investigations may later become the basis of an application for approval to market a new drug ("NDA") or a supplemental NDA.) Under the Federal Food, Drug, and Cosmetic Act and its regulations, an investigational new drug cannot be introduced into commerce unless it is the subject of an investigational new drug application, or "IND." 21 U.S.C. § 355(i); 21 C.F.R. § 312.20(a).

The regulation cited in support of this instruction, then, refers only to drugs that are being used in clinical investigations. The purpose of the regulation is to allow for the publication of the results of these investigations in journals and elsewhere as part of a scientific discussion; it is expressly <u>not</u> to allow the drug to be promoted as safe and effective for uses for which it has not been approved. There has been no evidence introduced that Wellbutrin SR was the subject of an IND during the relevant time period, and this regulation has no bearing on this case.

The defendant's proposed instruction also wrongly broadens the scope of this exception. As the defendant frames it, the exception applies "provided that the manufacturer does not represent in a promotional context that the product is *approved* for an off-label use" (emphasis added). In fact, the regulation limits the dissemination of scientific information regarding a drug subject to an IND only to situations where the manufacturer does not represent in a promotional context that the product "*is safe or effective* for the purposes for which it is under investigation or otherwise promote the drug." 21 C.F.R. § 312.7(a) (emphasis added). This is a critical distinction: while one study might imply safety and efficacy, the FDA's decision to approve a drug for a particular use must be based on an administrative finding of substantial evidence of safety and efficacy – which generally requires at least *two* published, peer-reviewed, and adequate and well-controlled studies. The defendant's instruction misstates the law in multiple ways, and, at a minimum, this portion of the instruction should be deleted.

More fundamentally, however, the instruction as a whole lacks balance and context. There is no dispute among the parties that off-label prescriptions are lawful, while off-label promotion is not. Both parties acknowledged as much in their opening statements, and all of the evidence so far has been consistent with that understanding of the law. Moreover, the defendant has not been charged with either writing off-label prescriptions or off-label marketing. There is no basis for instructing the jury so extensively on the merits of disseminating off-label information without also including an equally comprehensive discussion of the public health risks associated with off-label promotion. Last, instructing the jury on the opinion of a professional association is somewhat far afield from instructing the jury on the law that it should apply.

The government respectfully requests that, if the Court rejects the government's proposed instruction, the following statements be included in the defendant's version:

(1) "While off-label prescribing is a legally permitted practice, a drug manufacturer is not allowed to promote its drugs for off-label uses."

(2) "The defendant in this case is not charged with off-label promotion of prescription drugs."

The legally incorrect information discussed above should also be removed, as should reference to the American Psychiatric Association.

2. Count One: Obstruction of a Proceeding: Second Element – Obstructs, Influences, or Impedes, or Attempts to Do So (p. 66)

The United States has one small objection to the Court's proposed inserts: it asks that "made false *and* misleading statements to the FDA *and* withheld *and* concealed information" be changed to "made false *or* misleading statements to the FDA *or* withheld *or* concealed information." *See, e.g., United States v. Mackins*, 315 F.3d 399, 415-416 (4th Cir. 2003) (where indictment reads conjunctively, jury should be instructed disjunctively); *United States v. Gerhard*, 615 F.3d 7, 31 (1st Cir. 2010) (same).

3. Count One: Obstruction of a Proceeding: Third Element – An Official Proceeding (p. 69)

The United States respectfully objects to the inclusion of the following language in the Court's instruction on the third element of Count One, as it is inconsistent with the statute: "and the defendant must have intended to affect the proceeding." The United States requests the following language instead: "and the defendant must have intended to affect a potential or foreseeable proceeding."

4. Count Two: Falsification/Concealment of Documents: Elements of the Offense (pp. 71-72) and Count Two: Concealment or Falsification of Records: Second Element – Knowingly, With Intent to Impede, Obstruct or Influence (p. 75)

The defendant's version of these instructions (which the Court proposes to adopt) omits a reference to document alteration – a means of violating 18 U.S.C. § 1519 charged in the Indictment, of which proof was offered during trial. In addition, the defendant's version omits a reference to the fact that the defendant may have violated § 1519 by acting with the requisite intent and in relation to or in contemplation of an FDA investigation. *See* 18 U.S.C. § 1519 (outlawing falsification and concealment of documents "in relation to or contemplation of any such matter or case").

5. Counts Three through Six: Making False Statements: The Indictment and Statute (p. 70)

The Court proposes giving the jury a handout listing each of the false statements charged. The United States has prepared a proposed handout and will provide it to the Court and the defendant.

6. Counts Three Through Six: Making False Statements: Third Element – Trick, Scheme or Device or False, Fictitious or Fraudulent Statement (p. 82)

The United States respectfully suggests the following inserts to the Court's proposed instruction on the third element of Counts Three to Six.

GOVERNMENT PROPOSED INSERTS

(Counts Three Through Six: Making False Statements: Third Element – Trick, Scheme or Device or False, Fictitious or Fraudulent Statement)

The third element the government must prove beyond a reasonable doubt for Counts Three through Six is that:

(1) the defendant falsified, concealed or covered up a fact by trick, scheme or device; or

(2) the statement or representation made by the defendant was false, fictitious or fraudulent.

A scheme is a plan for the accomplishment of an object. A trick or device is a deceptive act or strategy calculated to deceive other persons.

A statement or representation is "false" or "fictitious" if it was untrue when made, and known at the time to be untrue by the person making it or causing it to be made. A statement or representation is "fraudulent" if it was untrue when made and was made or caused to be made with the intent to deceive the government agency to which it was submitted.

In Count Three, the government contends that the so called trick, scheme or device employed by the defendant was: **(1) withholding or concealing documents and information, despite having represented that she would cooperate with the FDA; (2) withholding or concealing documents, despite having represented that she would provide the documents requested to the extent she could obtain them; or (3) making a series of false or misleading statements to the FDA concerning the nature and scope of off-label materials and activities and other potentially illegal activities utilized by GSK.** The statements that the government contends were false, fictitious or fraudulent are:

- **"GSK has not developed, devised, established, or maintained any program or activity to promote or encourage, either directly or indirectly, the use of Wellbutrin SR as a means to achieve weight loss or treat obesity."**
- **"GSK's promotional material and activities for Wellbutrin SR are consistent with the approved Prescribing Information and the supporting clinical data."**

- **"As noted, GSK has not developed or maintained promotional plans or activities to directly or indirectly promote Wellbutrin SR for weight loss or the treatment of obesity."**
- **"GSK has two types of advisory boards - National Advisory Boards and Local Advisory Boards. . . . GSK, through its field-based Market Development Managers, has established Local Advisory Boards in certain sales regions for the purpose of obtaining specific advice from health care professionals in that locale for Wellbutrin SR and/or issues relating to the therapeutic area of depression. Pursuant to GSK policy, no sales region may have more than two Local Advisory Boards, and no such board may meet more than twice per year."**

In Count Four, the government contends that the so called trick, scheme or device employed by the defendant was: **(1) withholding or concealing documents and information, despite having represented that she would cooperate with the FDA; (2) withholding or concealing documents, despite having represented that she would provide the documents requested to the extent she could obtain them; (3) altering or deleting portions of documents, despite having represented that she would cooperate with the FDA; or (4) making a false or misleading statement regarding GSK's compensation practices for doctors.** The statement that the government contends was false, fictitious or fraudulent is: **"Attendees were not paid, reimbursed, or otherwise compensated to attend these events, with the exception of reimbursement for parking fees in some cases."**

In Count Five, the government contends that the so called trick, scheme or device employed by the defendant was: **(1) withholding or concealing documents and information,**

despite having represented that she would cooperate with the FDA and indicating that her submissions were final and complete; (2) by withholding or concealing documents, despite having represented that she would provide the documents requested to the extent she could obtain them and indicating that her submissions were final and complete; or (3) by making false or misleading statements to the FDA concerning the nature and scope of off-label materials and activities and other potentially illegal activities utilized by GSK. The statements that the government contends were false, fictitious or fraudulent are:

- **"[W]e systematically and carefully collected, reviewed and provided you with extensive information and supporting documentation regarding GSK's promotional and non-promotional activities relating to Wellbutrin SR and weight loss. . . . In the final analysis, all of the information consistently and clearly points to the same conclusion - GSK has not developed, devised, established, or maintained any program or activity to promote, either directly or indirectly, the use of Wellbutrin SR to achieve weight loss or treat obesity."**
- **"GSK's promotional material and activities for Wellbutrin SR are consistent with the approved Prescribing Information and the supporting clinical data."**
- **"The extensive information that we have provided . . . objectively demonstrates that GSK has not engaged in the promotion of Wellbutrin SR for weight loss."**
- **"With this final submission, we complete our production of information and documents in response to the requests in your letter dated October 9, 2002 and additional requests raised in your teleconference with GSK on January 21, 2003 concerning Wellbutrin SR."**

In Count Six, the government contends that the so called trick, scheme or device employed by the defendant was: **(1) withholding or concealing documents and information, despite having represented that she would cooperate with the FDA and having indicated that her response was complete; (2) withholding or concealing documents, despite having represented that she would provide the documents requested to the extent she could obtain them and having representing that her response was complete; or (3) making a false or misleading statement to the FDA concerning the nature and scope of off-label materials and activities and other potentially illegal activities utilized by GSK.** The statement that the government contends was false, fictitious or fraudulent is: **"Although there were isolated deficiencies, the objective evidence clearly demonstrates that GSK has not developed, maintained, or encouraged promotional plans or activities to promote, directly or indirectly, Wellbutrin SR for weight loss, the treatment of obesity, or any other unapproved indication."**

As I have instructed you elsewhere, you must consider each of these counts separately.

Whether the defendant's behavior amounted to a trick, scheme or device, is a question for you, as finders of the facts to decide. Similarly, whether the specified statements were false, fictitious or fraudulent is a question for you, the finders of fact. In deciding whether the statements were false, fictitious or fraudulent, if the statements were ambiguous, so that they could be interpreted in several ways, then the government must prove that the statements were false under any reasonable interpretation in the circumstances.

For each count, it is the government's burden with respect to this element to prove beyond a reasonable doubt that the defendant falsified, concealed or covered up a material fact

by trick, scheme or device, or that the defendant's statement was false, fictitious or fraudulent.

7. Reference to a Potential Department of Justice Investigation

The Court's comments suggest that it questions whether the United States has presented evidence that the defendant intended to affect a Department of Justice investigation. In her own notes, the defendant makes repeated comments regarding criminal investigations that are in the jurisdiction of the Department of Justice. For example, on January 15, 2003, the defendant wrote:

> Describe Wellbutrin investigation
> - make it clear we have off-label speakers and off-label slides
> - likely outcome (Warning letter)
> - what would happen if we resist –> refer to OCI
> - injunction on use of speakers
> - seizures (warning letter on Zantac)
> - crime

Ex. 10E at 2. When the FDA's Office of Criminal Investigation ("OCI") wants a criminal prosecution to occur or wishes to institute a seizure action, it must get the Department of Justice ("DOJ") involved. Even more clearly, the defendant's concerns about doctors' prosecution under 18 U.S.C. § 1001. Ex. 10 at 64-65. The defendant's notes also repeatedly mention her concerns about qui tam actions, which also involve DOJ. Ex. 10 at 169, 187-88.

Dated: May 9, 2011

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on May 9, 2011, I caused a true and correct copy of the above-entitled THE UNITED STATES' COMMENTS ON THE COURT'S PROPOSED JURY INSTRUCTIONS to be served via the District Court's Electronic Filing System upon counsel of record as follows:

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